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PATENT  
Docket No.: 015662-000900US

On May 5, 2006

TOWNSEND and TOWNSEND and CREW LLP

By: *Lois M. Simón*  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Micheline Markey, John W. Shell,  
Bret Berner

Application No.: 09/432,881

Filed: November 2, 1999

For: PHARMACOLOGICAL  
INDUCEMENT OF THE FED MODE FOR  
ENHANCED DRUG ADMINISTRATION  
TO THE STOMACH

Confirmation No.: 1727

Examiner: Shirley Gembeh

Art Unit: 1614

RESPONSE - REQUEST FOR  
RECONSIDERATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated January 5, 2006, Applicants respectfully request reconsideration and reexamination of this Application on the basis of the comments below.

Claims are rejected over various references for anticipation and/or obviousness. However, inasmuch as Applicants believe that all of the claims under examination are patentable over said references, no claim amendments are made in this Response.

Claims 1-9, 14-26, 32-34, 47-55 and 97-151 are pending in this application.

Claims 1 and 14-18 are rejected as anticipated by McKenzie et al. This reference relates to the administration of sodium docusate, a surfactant known for use in

pharmaceutical compositions. The examiner points to information that shows the administration of docusate to rats in a toxicity feeding study in amounts that are within the disclosed fed mode inducing range disclosed in this Application.

However, claims 1 and 14-18 call for administration of fed mode inducing agents, including docusates, as part of a composition containing a drug retained in a solid matrix in a manner that causes release of the drug when the solid matrix is in the stomach. McKenzie et al. do not administer docusate in combination with a drug in a solid matrix, so that these claims are not anticipated by the reference, nor are they rendered obvious from it.

Claims 49-55, which call for pharmaceutical compositions containing a drug and specified types of fed mode inducing agents, are rejected as anticipated by WO 97/47285. However, this reference does not disclose compositions containing the claimed fed mode inducing agents, so these claims are not anticipated or rendered obvious from this reference. WO 97/47285 discloses administration only of serotonin receptor antagonists, fatty acids and salts, and L-tryptophan as fed mode inducing agents, and not any of those claimed herein.

Claims 1 and 14-18 stand rejected as anticipated by Kais et al. However, this reference discloses only the administration of docusate as a laxative, similar to the disclosure of references such as Acharya et al., which were distinguished previously in the prosecution of this application. The difference, as explained earlier, is that for use as a laxative, an ingredient is formulated so as to be effective in the colon, not in the stomach. In the present compositions the docusate is formulated for release into the stomach so as to induce the fed mode there. These claims thus are not anticipated or rendered obvious by Kais et al.

Claims 1-9 and 14-18 stand rejected as obvious over the combination of McKenzie et al. and WO 97/47285. However, the making of this combination is not supported by the art. WO 97/47285 discloses administration only of serotonin receptor antagonists, fatty acids and salts, and L-tryptophan. McKenzie et al. do not disclose

administration of docusate for any useful purpose other than its known use as a surfactant, but only disclose testing of its toxicity. There is no basis in the cited art for combining these references so as to come up with any combination of drugs in a matrix released into the stomach together with docusate, for use as a fed mode inducing agent in the stomach, especially in the absence of disclosure of fed mode inducement of docusate in both references. The claims are thus not rendered obvious by this proposed combination of references.

Claims 23-26, 47-48, 97-110, 116-120 and 123-124 are rejected as obvious over WO 97/47285 taken together with WO 99/25321 [the correct citation for WO 98/247502], further in view of Hagen et al., Shaffer et al. and Pupovac et al.

WO 99/25321 relates to compositions containing eprosartan for various purposes, and its relevance to the current claims is not seen. The claims do not call for the use of any and all thio-organic acids, but only the dithioorganic acids specified, and eprosartan is neither among this class nor related to it.

Hagen et al. disclose only that addition of alpha-lipoic acid to a diet of acetyl-L-carnitine aided that substance in improving metabolism and lowering oxidative stress. This is not seen to involve inducement of the fed mode. In addition, alpha-lipoic acid was not contained in any compositions in Hagen et al.; it was mixed with the food. A combination of references including Hagen et al. is thus not deemed to render claims to compositions containing a drug and alpha-lipoic acid as a fed mode inducing agent for release in the stomach, obvious.

Shaffer et al. disclose the use of 25 g xylitol as producing gastric emptying effects, but this quantity is outside the fed mode inducing range disclosed in this application. Accordingly, rejection of claims including Shaffer et al. as obvious is not supported.

Pupovac et al. likewise do not disclose fed mode inducing amounts. In addition, they disclose only gastric emptying effects from proteins generated from casein,

but do not disclose beta-casomorphin. Again, rejection of claims for obviousness including this reference is not warranted.

Claims 105 and 125-151 are rejected as obvious over WO 97/47285 taken together with Yaksh and Theeuwes et al. Yaksh teaches loperamide, but only in topical or local administration, not for internal administration, and does not disclose fed mode inducement by loperamide. Theeuwes et al. do not make up for the deficiencies of the other references.

Claims 1, 32-34 and 130-143 are rejected as obvious over WO 97/47285 and WO 99/25321 taken together with McKenzie et al., Hagen et al., Shaffer et al. and Pupovac et al., with respect to the inclusion of arginine and arginine salts, Trp-Trp dipeptides and alkylpyridinium salts. The disclosure of WO 97/47285 relied on by the examiner relates to the drugs administered in that reference, not to fed mode inducing agents, whereas the current claims call for the combinations of dipeptides and other claimed fed mode inducing agents with other drugs. Again, no basis for an obviousness rejection of these claims is seen in the cited art.

#### CONCLUSION

In view of the foregoing, Applicants submit that all claims under examination are directed to novel and nonobvious subject matter, and request issuance of a Notice of Allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,

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